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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,293	11/03/2003	Edward Nowak	3399-4006US1	6240

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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/701,293	<b>Applicant(s)</b> EDWARD NOWAK	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 15-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 15-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/030,902.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

*Humera N. Sheikh*  
HUMERA N. SHEIKH  
PRIMARY EXAMINER  
TC-1600

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/18/05; 07/29/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Preliminary Amendment and Applicant's Arguments/Remarks, both filed 05/18/06 and the Information Disclosure Statements (IDS) filed 07/18/05 and 07/29/05 is acknowledged.

Claims 1 and 15-50 are pending in this action. Claims 2-14 have been cancelled. New claims 48-50 have been added. Claims 1 and 15-50 are rejected.

### ***Inventorship***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Claim Objections***

Claim 15 is objected to because of the following informalities:

Independent Claim 15 appears to be identical to or a duplicate of Claim 1.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1 and 15-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (WO 97/35537).**

The instant invention is drawn to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

**Brown ('537)** discloses capsules, a method of encapsulation and an encapsulation apparatus, wherein the capsules comprise metered doses of substances to be encapsulated within the capsule, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance. The pairs of capsule halves are then brought together, sealed and cut, thus forming capsules containing the substance.

The method of encapsulation is characterized by supplying to an encapsulation unit, two films of like material capable of deforming elastically at least when partially solvated, and applying solvent to at least one of the films prior to encapsulation to cause partial solvation of the material surface, such that the partially solvated surface can adhere to and seal with the film material. The invention enables encapsulation using materials other than gelatin, such as

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polyvinyl alcohol. Further suitable materials include alginate, hydroxypropyl methyl cellulose and polyethylene oxide, for example (see page 6, lines 5-19 and Abstract).

**Claims 15, 16, 19, 20, 28-29, 31, 35-36, 38, 42, 43, 47 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (EPO 0 211 079 A1).**

The instant invention is drawn to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

**Ueda ('079)** discloses a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 17, 18, 21-27, 30, 32-34, 37, 39-41 and 44-46, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (EPO 0 211 079 A1) in view of Brown (WO 97/35537).**

The instant invention is drawn to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

**Ueda ('079)**, as discussed above, teaches a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Any material usually used for the shell of the soft capsules is usable for forming the shells and partition, such as gelatin, plasticizers, perfume, pigments, solubility, adjusting agents, etc. can be added as desired (pg. 11, lines 6-11).

The multicellular capsule may be of any shape, such as oval shape, oblong form, round form, tubular form or in the form of a suppository (pg. 11, lines 16-21).

The examples on pages 13-17 demonstrate the method of manufacturing the multicellular soft capsules.

Ueda is deficient only in the sense that he does not explicitly teach chambers containing metered doses of materials contained within the capsule.

**Brown ('537)** teaches capsules comprising metered doses of substances to be encapsulated within the capsule, carried out through injection, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance (see page 6, lines 5-19).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the capsules of Brown within the teachings of Ueda, because Brown

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explicitly teaches capsules that can efficiently comprise metered doses of substances contained within the capsule. The expected result would be an improved multicellular capsule comprising metered doses of varying substances for effective capsule delivery.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

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October 02, 2006

  
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